



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/729,026      | 12/05/2003  | Steven F. Bolling    | FORFLOW.1CP6C1      | 8833             |

20995 7590 02/08/2006

KNOBBE MARTENS OLSON & BEAR LLP  
2040 MAIN STREET  
FOURTEENTH FLOOR  
IRVINE, CA 92614

|          |
|----------|
| EXAMINER |
|----------|

LAYNO, CARL HERNANDZ

|          |              |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

3766

DATE MAILED: 02/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

②

|                              |                                      |                                       |  |
|------------------------------|--------------------------------------|---------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/729,026 | <b>Applicant(s)</b><br>BOLLING ET AL. |  |
|                              | <b>Examiner</b><br>Carl H. Layno     | <b>Art Unit</b><br>3766               |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 December 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 7,9,10,13,15-25 and 28-66 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 7,9,13,17-21,25,28-30,38-42 and 44-49 is/are allowed.
- 6) ☒ Claim(s) 10,15,24,31 and 43 is/are rejected.
- 7) ☒ Claim(s) 16,22,23,32-37 and 50-66 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. Acknowledgment is made of applicant's amendment, which was received by the Office on December 5, 2005.
2. Claims 1-6, 8, 11, 12, 14, 26, and 27 are canceled. Claims 33-66 have been added. Claims 7, 9, 10, 13, 15-25, and 28-66 are active.

#### ***Claim Objections***

3. Claim 43 is objected to because of the following informalities: -Claim 43 is objected to under 37 CFR 1.75(b) since it does not "differ substantially" from the subject matter already recited in claim 34. Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:  

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
5. Claim 43 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, there is no antecedent basis in the claim language for the terms "the first peripheral vessel" and "the second vessel". To overcome this rejection, the Examiner recommends changing the claim dependency to depend from claim 29 rather than from claim 31.

***Claim Rejections - 35 USC § 102***

6. Upon further reconsideration of applicant's claim cancellations and claim amendments, the Examiner is withdrawing the 35 U.S.C 102(b) rejections based upon the articles of Vekerke et al and Ide et al, which were made against claims 11, 12, 14, 26, 27, and 32 in the last Office action.

***Double Patenting***

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thornton*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 15 and 31 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 2 of U.S. Patent No. 6,387,037. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claim the features of blood pumps capable of pumping blood at subcardiac flow rates and a "conduit", specified in claim 2 of the '037 patent as a multi-lumen catheter, for permitting blood

Art Unit: 3766

flow in reverse directions between two different blood vessels through subsidiary conduits.

Although applicant's claim 31 specifies that the conduit is constructed of a flexible material, the Examiner is taking the position that it would be obvious, if not inherent, for the multi-lumen catheter w/conduits of claim 2 in the '037 patent to be composed of a flexible material, since such a catheter would have to be flexible enough to have been guided through blood vessels into its targeted position within the patient's vasculature.

9. Claims 10 and 24 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 8, and claims 1 and 7, respectively, of U.S. Patent No. 6,889,082. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons. Claim 1 of the '082 patent recites the same primary features of an extracardiac pump for pumping blood at subcardiac flow rates and a "first conduit" capable of permitting the flow of blood in two directions since it also houses a "second conduit". The distal end of this "second conduit" may reside either in the same blood vessel as the "first conduit" or a different blood vessel. The "first conduit" is fluidly coupled to a blood vessel using a minimally invasive procedure at a single site. The claim does not recite the location of the pump (i.e. whether or not it is inside or outside of the patient's body) or what type of pump it is. Depending claim 8 of the '082 patent specifies that the pump is implantable within the patient's body. Depending claim 7 of the '082 patent specifies that the pump is a rotary pump. To have combined these dependent claims with independent claim 1 of the '082 patent to form new independent claims, as done in independent claims 10 and 24 of this application, would have been an obvious expedient to one of ordinary skill.

*Allowable Subject Matter*

10. Claims 16, 22, 23, 32-37, and 50-66 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

11. Claims 7, 9, 13, 17-21, 25, 28-30, 38-42, and 44-49 are allowed.

*Conclusion*

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The Jarvik et al (US 5,965,089) patent is cited for its pertinent pump arrangement (Fig.20). Unlike applicant's device, however, one conduit of Jarvik et al is not located within a blood vessel, but rather is located in the patient's left ventricle. It is unclear whether or not the device of Jarvik et al provides pumping of blood at "subcardiac" rates.

The Troutner et al (US 4,464,164) patent describes a dialysis machine whose structure is similar to that of applicant's device in that rotary pumps **20,80** (Fig.3) are used to circulate blood through a single conduit **134**. Unlike applicant's device, the single conduit **134** arrangement of Troutner et al does not provide flow to two different blood vessels or locations in the vasculature.

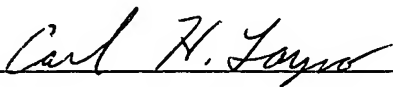
*Conclusion*

Art Unit: 3766

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carl H. Layno whose telephone number is (571) 272-4949. The examiner can normally be reached on 9/4/5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
\_\_\_\_\_  
CARL LAYNO  
PRIMARY EXAMINER

CHL  
2/2/2006